DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 25 2000

James R. Phelps, Esquire
Hyman, Phelps & McNamara, P.C.
1120 G Street, N.W.
Washington, D.C. 20005

Re: Citizen Petition #92P-0409

Dear Mr. Phelps:

This is our final response to the October 19, 1992, citizen petition that was submitted to the Food and Drug Administration (FDA or agency) on behalf of several veterinarians. The citizen petition asks that FDA issue regulations regarding the professional activities of licensed veterinarians, specifically that FDA propose regulations to: (1) permit veterinarians to prescribe, administer, and dispense legally available drug products for any use consistent with the standards of their profession; and (2) provide that licensed veterinarians may, within the scope of their practice, compound legally available drug products for any purpose.

Since receiving your citizen petition, FDA has proposed, and finalized, regulations on this topic. FDA issued a final rule that allows veterinarians to prescribe extralabel use of certain approved animal and human drugs for animals (21 CFR Part 530). This rule, which implements the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), provides veterinarians greater flexibility for using approved drugs for animal use. Section 530.13 of the rule defines the conditions under which a veterinarian is permitted to compound a product from approved animal or human drugs.

Sincerely yours,

John M. Taylor, III
Associate Commissioner
for Regulatory Affairs

cc: HFA-305 (Docket 92P-0409)

92P-0409

LET 2